



S/N 09/125,953

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	FODSTAD et al.	Examiner:	Sisson, B.
Serial No.:	09/125,953	Group Art Unit:	1655
Filed:	December 10, 1998	Docket No.:	7885.56USWO
Title:	IMMUNO-MAGNETIC CELL SEPARATION USED IN IDENTIFICATION OF GENES ASSOCIATED		

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: X551962
Date of Deposit: March 15, 2001

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By: 
Name: Brian Maharaj

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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Dear Sir:

In response to the Office Action dated November 15, 2000, with the time for response extended with a one month extension of time to March 15, 2001, please amend the aforementioned patent application as indicated herein.

In the Claims

Please amend claim 12 as follows. In view of rule changes to 37 C.F.R. §1.121, a clean version of amended claim 12 is presented as below. Also enclosed herewith is an attachment of a mark-up copy with revisions to claim 12 shown.

12. (Amended) Method for identifying genes differentially expressed between cells isolated from different tissues, the method comprising:

A. detecting target cells from a first and a second tissue;

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- Reconsideration*
- B. obtaining nearly 100% specific target cells by repeatedly immunomagnetically isolating said first and second tissue target cells;
 - C. determining levels of mRNA expression within said first and second tissue target cells;
 - D. comparing the levels of mRNA expression in said first and second tissue target cells; and
 - E. based upon the comparison in step D, identifying the genes differentially expressed between said first and second tissue target cells, wherein at least one of said first and second tissue target cells are tumor cells, in order to recognize previously unknown genes possibly involved in determining metastatic characteristics of cancer cells.
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Please cancel claims ~~1~~ and ~~4~~ without prejudice or disclaimer.

Remarks

Reconsideration is respectfully requested in view of the above amendments and following remarks. The revisions to claim 12 are supported, for instance, on page 1, lines 8-23, in Applicants' specification. In view of rule changes to 37 C.F.R. §1.121, a clean version of amended claim 12 is as above. Also enclosed herewith is an attachment of a mark-up copy with revisions to claim 12 shown. Claims 1 and 4 are canceled. Claims 2, 3, 5-9 and 12 are pending.

Claim 1 is rejected under 35 U.S.C. 112 as being indefinite. The rejection is rendered moot, as claim 1 has been canceled. Withdrawal of the rejection is respectfully requested.

Claims 1-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Høifødt et al. Applicants respectfully traverse this rejection, and respectfully request reconsideration in view of the following comments.

Claim 12 recites a method comparing the levels of mRNA expression in target cells of a first tissue to the target cells of a second tissue. Moreover, from this comparison, genes differentially expressed between the target cells of the tissues are identified, in order to recognize

previously unknown genes possibly involved in determining metastatic characteristics of cancer cells. Høifødt et al. is related to an immunoassay method for detection and isolation of specific target cells. However, the cited reference does not disclose or teach a method of comparing levels of mRNA expression to identify genes differentially expressed in two target cells. Also, Høifødt et al. does not demonstrate or provide any experimental evidence related to comparative examination of transcripts from two cells in order to recognize genes with previously unknown gene expression patterns, sequences and functions. Therefore, it is respectfully submitted that claim 12 is not anticipated by the cited reference.

Furthermore, it is neither obvious nor reasonable to suggest in the cited reference to compare levels of mRNA and identify genes differentially expressed in recognizing unknown genes involved with metastatic characteristics of cancer cells. Accordingly, it is respectfully submitted that claim 12 is patentable over Høifødt et al. Withdrawal of the rejection is respectfully requested.

Claims 1-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Høifødt et al. in view of Fodstad et al. (*Journal of Cellular Biochemistry*(1994)). Applicants respectfully traverse this rejection, and respectfully request reconsideration in view of the following comments.

For at least the same reasons above, Høifødt et al. fails to disclose or teach the recited claim 12. Further it would not be reasonable to suggest that Høifødt et al. and Fodstad et al. either alone, or in combination would arrive at the claimed invention. Fodstad et al. have not "cloned various tumor cells", but have only selected various tumor cells. Fodstad et al. does discuss the role of the microenvironment in determining characteristics of metastatic cells. The cited reference also mentions the importance of individual tumor cell characteristics for metastatic formation, and further relating differences in a particular characteristic, between cell sublines, cell clones, or different cell lines. However, Fodstad et al. does not teach or suggest a method involving identifying unknown genes for determining metastatic characteristics of cancer cells as in claim 12. Furthermore, there is no suggestion and it is not obvious in Fodstad et al. to compare levels of mRNA expression in obtaining identification of genes differentially expressed in order to recognize previously unknown genes. Therefore, Fodstad et al. does not remedy the

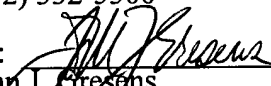
deficiencies of Høifødt et al., and the claimed invention is not obvious in view of the cited references. As above, claim 12 has been established as patentable, and claims 2-3 and 5-9 depend from and further limit claim 12. It is respectfully submitted that claims 2-3 and 5-9 are also patentable for at least the same reasons with respect to claim 12. Withdrawal of the rejection is respectfully requested.

With the above amendments and remarks, Applicants respectfully submit that the claims now pending in this patent application are in condition for allowance. Favorable consideration is respectfully requested. If any further questions arise, the Examiner is invited to contact Applicants' representative at the number listed below.

Respectfully submitted,

MERCHANT & GOULD, P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
(612) 332-5300

Dated: March 15, 2001

By: 
John J. Gressens
Reg. No. 33,112

JJG/BAW/pjr

